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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,997	08/16/2005	Ian David Worthington	Q85312	5134
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SUITE 800				
WASHINGTON, DC 20037				
EXAMINER				
DOUGLAS, STEVEN O				
ART UNIT		PAPER NUMBER		
3771				
MAIL DATE		DELIVERY MODE		
06/25/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,997

Applicant(s)

DAVID WORTHINGTON, IAN

Examiner

/Steven O. Douglas/

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Hegwood (US 6,668,831).

The Hegwood reference discloses a tracheostomy cannula mounting comprising a planar sheet 2.13 (i.e. made in accordance with sheet 13, see also col. 8, lines 30-36) with an associated channel (see aperture 2.15), wherein the sheet includes an adhesive layer that is comprised of tacky gel-type materials such as gum, etc..

In regard to claim 10, the method as claimed would be inherent during normal use and operation of the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hegwood in view of Kaiser'237.

The Hegwood reference discloses an adhesive sheet (*supra*), but does not disclose a removable protective layer of non-tacky material. The Kaiser'237 reference discloses another adhesive sheet that utilizes a removable protective layer of non-tacky material 14 to protect the adhesive sheet prior to use. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a removable protective layer of non-tacky material with the Hegwood device in view of the teachings of the Kaiser'237 reference to protect the adhesive sheet prior to use.

Claims 1-6,9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bridge'011 in view of Hegwood.

The Bridge reference discloses a tracheostoma cannula device 160 (see Figure 9) with associated flange portion, but does not disclose use of a mounting. The Hegwood reference discloses another tracheostoma device (*supra*) that utilizes a mounting (*supra*) in order to provide an enhanced sealing interface. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a mounting with the cannula device of Bridge in view of the teachings of the Hegwood to provide an enhanced sealing interface.

In regard to claim 10, the method as claimed would be inherent during normal use and operation of the device resulting from the combined teachings.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hegwood.

The Hegwood reference discloses an adhesive sheet (supra), but does not disclose the sheet as being of a thickness between 1 and 7 mm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the sheet be between 1 and 7 mm in thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 1-10 and 12 have been considered but are moot in view of the new ground(s) of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Rubin et al. and Lambert references pertain to other tracheostoma devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
Art Unit 3771

SD
6/20/08